EPA/540/R/99/005
OSWER 9285.7-02EP
PB99-963312
September 2001

Risk Assessment Guidance for Superfund
Volume I: Human Health Evaluation Manual
(Part E, Supplemental Guidance for Dermal Risk Assessment)
Interim

Review Draft - For Public Comment

Office of Emergency and Remedial Response
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Washington, D.C. 20460

DISCLAIMER

This document provides guidance to EPA Regions concerning how the Agency intends to exercise its discretion in implementing one aspect of the CERCLA remedy selection process. The guidance is designed to implement national policy on these issues.

Some of the statutory provisions described in this document contain legally binding requirements. However, this document does not substitute for those provisions or regulations, nor is it a regulation itself. Thus, it cannot impose legally-binding requirements on EPA, States, or the regulated community, and may not apply to a particular situation based upon the circumstances. Any decisions regarding a particular remedy selection decision will be made based on the statute and regulations, and EPA decisionmakers retain the discretion to adopt approaches on a case-by-case basis that differ from this guidance where appropriate. EPA may change this guidance in the future.

ABOUT THIS DOCUMENT

WHAT IT IS This document is Interim Supplemental Guidance (Part E) to the *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (RAGS)*. This document incorporates and updates the principles of the EPA interim report, *Dermal Exposure Assessment: Principles and Applications* (DEA) (U.S. EPA, 1992a), released by the Office of Health and Environmental Assessment (OHEA), in the Office of Research and Development (ORD), in January 1992. RAGS Part E is intended to provide a consistent methodology for assessing the dermal pathway for Superfund human health risk assessments and supersedes any previous dermal risk assessment guidance.

FOR WHOM This guidance document is for risk assessors, risk assessment reviewers, remedial project managers (RPMs), and risk managers involved in Superfund site investigations and human health risk assessments.

WHAT IS NEW RAGS Part E updates or expands the following elements in dermal risk assessment methodology:

- updated dermal exposure assessment equations for the water pathway
- updated table for screening contaminants of potential concern (COPCs) from contaminants in water
- specific dermal absorption from soil values for ten chemicals and recommended defaults for screening other organic compounds
- updated soil adherence values based on receptor activities
- updated dermal exposure parameters that are consistent with the *Exposure Factors Handbook* (U.S. EPA, 1997a)
- an expanded Uncertainty Analysis section that discusses and compares the contribution of specific components to the overall uncertainty in a dermal risk assessment.

PEER REVIEW This guidance document has been reviewed by internal EPA peer review (May 1997), external peer review (January 1998), and followup external peer review (January 2000). In addition, specific technical recommendations were provided by a Peer Consultation Workshop organized by the Risk Assessment Forum (December 1998).

DISTRIBUTION PLAN This guidance document is being released as an interim document designated as RAGS Part E. This release accompanies a Federal Register Notice requesting public comment and soliciting additional data. Specific information and data tables within this document are available on the

EPA WebPage:

http://www.epa.gov/superfund/programs/risk/ragse/index.htm

ABOUT THIS DOCUMENT(continued)

WHERE TO SEND COMMENTS

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ACKNOWLEDGMENTS

This guidance was developed by the Superfund Dermal Workgroup, which included Regional and Headquarters staff in EPA's Office of Emergency and Remedial Response (OERR), staff in the EPA's Office of Research and Development (ORD), and staff from the Texas Natural Resource Conservation Commission. Jim Konz, Elizabeth Lee Hofmann, Steve Ells, and David Bennett of Headquarters OERR provided project management and technical coordination of its development.

OERR would like to acknowledge the efforts of all the Superfund Dermal Workgroup members who supported the development of the interim guidance by providing technical input regarding the content and scope of the guidance.

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OERR would also like to acknowledge the efforts of the peer review panel members who provided input on the draft version of the document.

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CDM Federal Programs Corporation provided technical assistance to EPA in the development of this guidance, under Contract Nos. 68-W9-0056 and 68-W5-0022.

PREFACE

This guidance is the fifth part (Part E) in the series *Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual* (RAGS/HHEM) (U.S. EPA, 1989). Part A of this guidance describes how to conduct a site-specific baseline risk assessment. Part B provides guidance for calculating risk-based concentrations that may be used, along with applicable or relevant and appropriate requirements (ARARs) and other information, to develop preliminary remediation goals (PRGs) during project scoping. PRGs and final remediation levels can be used throughout the analyses in Part C to assist in evaluating the human health risks of remedial alternatives. Part D complements the guidance provided in Parts A, B and C and presents approaches to standardizing risk assessment planning, reporting and review. Part E is intended to provide a consistent methodology for assessing the dermal pathway for Superfund human health risk assessments. It incorporates and updates principles of the EPA interim report, *Dermal Exposure Assessment: Principles and Applications* (U.S. EPA, 1992a).

Several appendices are included in this guidance to support the summary calculations presented in the main body of the document (Appendix A), to provide physical constants for specific chemicals (Appendix B), and to provide tables for screening chemicals for the pathway (Appendix C). Appendix D provides sample calculations.

ACRONYMS/ABBREVIATIONS

Acronym/ Abbreviation	Definition
a, b, c	Correlation coefficients which have been fitted to the Flynn's data to give Equation 3.8
ABS	Dermal absorption from soil
ABS_d	Fraction of contaminant absorbed dermally (dimensionless)
ABS_{GI}	Fraction of contaminant absorbed in gastrointestinal tract (dimensionless)
AF	Adherence factor of soil to skin (mg/cm^2-event)
ARARs	Applicable or Relevant and Appropriate Requirements
AT	Averaging time (days)
$	Constant specific for the medium through which diffusion is occurring
B	Dimensionless ratio of the permeability coefficient of a compound through the stratum corneum relative to its permeability coefficient across the viable epidermis (dimensionless)
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
BW	Body weight (kg)
CF	Conversion factor (10^{-6} kg/mg)
COC	Contaminant of Concern
COPC	Contaminant of Potential Concern
cPAH	Carcinogenic polynuclear aromatic hydrocarbons
C_{soil}	Chemical concentration in soil (mg/kg)
C_{tot}	Total concentration of chemical in the aqueous solution (mg/l)
C_u	Concentration of the non-ionized species (mg/l)
C_w	Chemical concentration in water (mg/cm^3)
DA_{event}	Absorbed dose per event (mg/cm^2-event)
DAD	Dermal absorbed dose (mg/kg-day)
D_e	Effective diffusivity of the absorbing chemical in the epidermis (cm^2/hr)
D_o	Diffusivity of a hypothetical molecule with a molecular volume (MV) = 0 (cm^2/hr)
D_{sc}	Effective diffusion coefficient of the chemical through the stratum corneum
DEA	Dermal Exposure Assessment: Principles and Applications (U.S. EPA, 1992a)
ED	Exposure duration (years)

EF	Exposure frequency (days/year)

ACRONYMS/ABBREVIATIONS (continued)

Acronym/ Abbreviation	Definition
EFH	Exposure Factors Handbook (U.S. EPA, 1997a)
EPA	U. S. Environmental Protection Agency
EPC	Exposure point concentration
EPD	Effective Prediction Domain
EV	Event frequency (events/day)
FA	Fraction absorbed water (dimensionless)
FTSA	Fraction of total surface area for the specified body part
GI	Gastrointestinal
GSD	Geometric standard deviation
HHEM	Human Health Evaluation Manual
IR	Water ingestion rate (liters/day)
K_{ew}	Equilibrium partition coefficient between the epidermis and water for the absorbing chemical (dimensionless)
K_{ow}	Octanol/water partition coefficient (dimensionless)
K_p	Dermal permeability coefficient of compound in water (cm/hr)
$K_{p\text{-}msd}$	Measured dermal permeability coefficient of compound in water (cm/hr)
$K_{p\text{-}pred}$	Predicted dermal permeability coefficient of compound in water (cm/hr)
$K_{p,ve}$	Steady-state permeability coefficient through the viable epidermis (ve) (cm/hr)
$K_{sc/w}$	Equilibrium partition coefficient between the stratum corneum and water (chemical specific dimensionless)
L_e	Effective thickness of the epidermis (cm)
l_{sc}	Apparent thickness of stratum corneum (cm)
MV	Molar volume (cm^3/mole)
MW	Molecular weight (g/mole)
IRIS	Integrated Risk Information System
NCEA	National Center for Environmental Assessment
OERR	Office of Emergency and Remedial Response

OHEA	Office of Health and Environmental Assessment

ACRONYMS/ABBREVIATIONS (continued)

Acronym/ Abbreviation	Definition
ORD	Office of Research and Development
OSWER	Office of Solid Waste and Emergency Response
$P_{particle}$	Particle density (g/cm^3)
PAH	Polynuclear aromatic hydrocarbon
PCBs	Polychlorinated biphenyls
pK_a	Chemical specific ionization constant
PRG	Preliminary Remediation Goals
RAGS	Risk Assessment Guidance for Superfund (U.S. EPA, 1989)
RfD	Reference dose
RfD_{abs}	Absorbed reference dose (mg/kg-day)
RfD_o	Reference dose oral (mg/kg-day)
RME	Reasonable maximum exposure
SA	Skin surface area available for contact (cm^2)
SC	Stratum corneum
SCS	Soil Conservation Service
SEE	Standard error of the estimator
SF	Slope factor
SF_{abs}	Absorbed slope factor $(mg/kg-day)^{-1}$
SF_o	Oral slope factor $(mg/kg-day)^{-1}$
SF_d	Dermal cancer slope factor $(mg/kg-day)^{-1}$
SFS_{adj}	Age-adjusted dermal exposure factor (mg-yrs/kg-event)
SVOCs	Semivolatile organic compounds
TCDD	Tetrachlorodibenzo-p-dioxin
J_{event}	Lag time per event (hr/event)
t^*	Time to reach steady-state (hr)
t_{event}	Event duration (hr/event)
THQ	Target Hazard Quotient (non-cancer)

TRL	Target Risk Level (cancer)

ACRONYMS/ABBREVIATIONS (continued)

Acronym/ Abbreviation	Definition
t_{sc}	Turnover time for the stratum corneum (days)
95% CL	95% confidence level
95% LCL	95% lower confidence level
95% UCL	95% upper confidence level